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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,429	06/15/2000	Raymond Paul Goodrich JR.	27-98B	1651

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GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER	
CHORBAJI, MONZER R	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/596,429	GOODRICH ET AL.
	Examiner	Art Unit
	MONZER R CHORBAJI	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This non-final office action is in response to the amendment received on 12/11/2003

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-77, 104-105 and 107-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,258,577 in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

With respect to claims 1, 50, 59, 68, 104 and 107, claim 1 of the ('577) reference teaches a method of inactivating a fluid (including blood constituents such as platelets) containing microorganisms by adding a certain amount of an endogenous photosensitizer then exposing the fluid along with the photosensitizer to a photoradiation source in order to activate the photosensitizer and inactivate the microorganisms. However, with respect to claims 1, 50, 59, 68, 104 and 107 the claims of the ('577) reference fails to teach the step of adjusting the percentage of plasma in the fluid to a desired value such as the fluid contains a plasma content of between

about 0% to about 50%. More specifically, the ('577) reference fails to teach the steps of mixing the photosensitizer along with the fluid and placing the fluid in a photopermeable container as disclosed in claims 1, 50 and 104. The ('337) reference teaches mixing the photosensitizer along with the fluid (col.24, lines 59-61) and placing the fluid in a photopermeable container (col.25, lines 13-15) such that the cuvette is photopermeable (col.17, lines 39-40). In addition, the ('337) reference teaches adjusting the plasma (bilirubin) content to about 30% of the total volume (col.24, lines 51-61). The 30% volume is based on 70:30 volume-to-volume ratios for a total volume of 100 ml. Furthermore, the ('337) reference teaches (col.24, lines 49-62) adding the stock solution to a solution containing plasma only (100% content of plasma in the fluid). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the method claims of U.S. Patent No. 6,258,577 to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 2, 4-13, 15-23, 26-27, 31-38, 40-49, 53-58, 75-77 and 108, the ('337) teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62), saline (col.13, line 13), buffer (col.13, line 13), nutrients (col.13, lines 16-19), phosphate (col.13, lines 27-28), cell storage solution (col.13, lines 16-19), an anticoagulant (col.12, lines 45-46), a cryoperservative solution (col.13, lines 25-29), washing the fluid (col.24, lines 60-62), photosensitizer is a photo-activatable compound (col.6, lines 4-10),

photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.5, line 55), bacterial (col.4, line 15), HIV viruses (col.4, line 17), photoradiation in the visible spectrum (col.8, lines 64-65), photoradiation in the ultraviolet spectrum (col.8, line 63), photoradiation is in both the visible and ultraviolet spectra (col.8, lines 64-66), half the light in the visible spectrum and the other half in the ultraviolet spectrum (col.8, lines 66-67), plasma is adjusted to be within about 0 to about 50 percent of the total volume of the fluid (col.24, lines 60-62), photosensitizer is added to anticoagulant and the anticoagulant is added to the fluid (col.9, lines 65-67), enhancer is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5), adenine (col.10, line 5), flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56), fluid and photosensitizer are contained in a photoradiation transparent container (col.10, lines 55-56), agitating during exposing (col.9, lines 57-61), placing fluid in a container transparent to photoradiation then adding photosensitizer to fluid and agitating the container (col.24, lines 60-62 and col.9, lines 57-61), adjusting the percentage of plasma before placing fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15), plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35), adding nutrients (coll13, lines 16-19), nutrients and photosensitizer are present in the container prior to addition of fluid (col.18, lines 42-44), blood constituents (col.4, line 41), whole blood (col.4, line 39), separated blood product (col.4, lines 41-43), consists essentially of platelets (col.24, lines 51-52), consists essentially of serum (col.4, lines 42-43), consists essentially of plasma (col.4, line 32), consists essentially of red blood cells (col.4, lines 41-42), adding sufficient additives so that proteins remains biologically

active after exposing (col.10, lines 2-4), photosensitizer is present at a concentration of between about 1 to about 200 micromolar (col.24, lines 61-63), photoradiation is between about 400 and about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61), photoradiation is between about 100 and about 200 nm (col.9, lines 49-50), therapeutic protein (col.4, lines 44-45), factor VIII (col.4, line 46), a support surface substantially parallel to the source of light (figure 7, 164), light emitting diodes (figure 7, 160), a reflective surface (figure 7, 163), a light guide (figure 7, 162), a temperature monitor (figure 7, 192), temperature controller such as a fan (col.17, lines 41-43), means for flowing the fluid (figure 7, 170, 184, 186, and 188), container is a transparent plastic bag (col.28, example 12), container is a transparent rigid plastic container (figure 7, 164), a shaker table (col.9, line 57), photopermeable container contains photosensitizer prior to addition of fluid (col.18, lines 42-44) and a lowered plasma content than occurs naturally (col.13, lines 18-19).

With respect to claims 28-29, 51-52, 60-61 and 69, the ('337) reference adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. However, adjusting the plasma content to other concentration values is a matter of routine experimentation.

With respect to claims 3 and 39, the ('337) reference adjusts the plasma content either before adding the photosensitizer or while adding the photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, the ('337) reference teaches diluting the plasma content (col.13, lines 18-19) such that it would be obvious to one having ordinary skill in the art to adjust the plasma either

before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claim 14, the ('337) reference teaches washing or reducing the content of the plasma (col.13, lines 18-19). However, it would be obvious to one having ordinary skill in the art to wash the plasma as many times as required in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 24-25, the ('337) reference teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2) such that it would be obvious to use various ratios of visible and ultraviolet spectra in order for the radiation to completely inactivate microorganisms present therein.

With respect to claim 30, the ('337) reference teaches adjusting the content of plasma in the fluid, but fails to disclose such a range. However, it would be obvious to one having ordinary skill in the art to adjust the content of plasma in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 62-67, 70-74, and 105, such claims are already discussed above with regard to claims 16, 55-58, and 102.

Claim Rejections - 35 USC § 103

5. Claims 1-77, 104-105 and 107-108 are rejected under 35 U.S.C. 103(a) as being obvious over Goodrich, Jr. et al (U.S.P.N. 6,258,577) in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

With respect to claims 1, 50, 59, 68, 104 and 107, the ('577) reference teaches a method of inactivating a fluid (including blood constituents such as platelets) containing microorganisms by adding a certain amount of an endogenous photosensitizer then exposing the fluid along with the photosensitizer to a photoradiation source in order to activate the photosensitizer and inactivate the microorganisms (col.23, lines 15-29). However, with respect to claims 1, 50, 59, 68, 104 and 107, the ('577) reference fails to teach the step of adjusting the percentage of plasma in the fluid to a desired value such as the fluid contains plasma content of between about 0% to about 50%. More specifically, the ('577) reference fails to teach the steps of mixing the photosensitizer along with the fluid and placing the fluid in a photopermeable container as disclosed in claims 1, 50 and 104. The ('337) reference teaches the following mixing the photosensitizer along with the fluid (col.24, lines 59-61) and placing the fluid in a photopermeable container (col.25, lines 13-15) such that the cuvette is photopermeable (col.17, lines 39-40). In addition, the ('337) reference teaches adjusting the plasma (bilirubin) content to about 30% of the total volume (col.24, lines 51-61). The 30% volume is based on 70:30 volume-to-volume ratios for a total volume of 100 ml. Furthermore, the ('337) reference teaches (col.24, lines 49-62) adding the stock solution to a solution containing plasma only (100% content of plasma in the fluid). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the ('577) reference to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 2, 4-13, 15-23, 26-27, 31-38, 40-49, 53-58, 75-77 and 108, the ('337) reference teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62), saline (col.13, line 13), buffer (col.13, line 13), nutrients (col.13, lines 16-19), phosphate (col.13, lines 27-28), cell storage solution (col.13, lines 16-19), an anticoagulant (col.12, lines 45-46), a cryoperservative solution (col.13, lines 25-29), washing the fluid (col.24, lines 60-62), photosensitizer is a photo-activatable compound (col.6, lines 4-10), photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.5, line 55), bacterial (col.4, line 15), HIV viruses (col.4, line 17), photoradiation in the visible spectrum (col.8, lines 64-65), photoradiation in the ultraviolet spectrum (col.8, line 63), photoradiation is in both the visible and ultraviolet spectra (col.8, lines 64-66), half the light in the visible spectrum and the other half in the ultraviolet spectrum (col.8, lines 66-67), plasma is adjusted to be within about 0 to about 50 percent of the total volume of the fluid (col.24, lines 60-62), photosensitizer is added to anticoagulant and the anticoagulant is added to the fluid (col.9, lines 65-67), enhancer is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5), adenine (col.10, line 5), flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56), fluid and photosensitizer are contained in a photoradiation transparent container (col.10, lines 55-56), agitating during exposing (col.9, lines 57-61), placing fluid in a container transparent to photoradiation then adding photosensitizer to fluid and agitating the container (col.24, lines 60-62 and col.9, lines 57-61), adjusting the percentage of plasma before placing

fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15), plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35), adding nutrients (coll13, lines 16-19), nutrients and photosensitizer are present in the container prior to addition of fluid (col.18, lines 42-44), blood constituents (col.4, line 41), whole blood (col.4, line 39), separated blood product (col.4, lines 41-43), consists essentially of platelets (col.24, lines 51-52), consists essentially of serum (col.4, lines 42-43), consists essentially of plasma (col.4, line 32), consists essentially of red blood cells (col.4, lines 41-42), adding sufficient additives so that proteins remains biologically active after exposing (col.10, lines 2-4), photosensitizer is present at a concentration of between about 1 to about 200 micromolar (col.24, lines 61-63), photoradiation is between about 400 and about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61), photoradiation is between about 100 and about 200 nm (col.9, lines 49-50), therapeutic protein (col.4, lines 44-45), factor VIII (col.4, line 46), a support surface substantially parallel to the source of light (figure 7, 164), light emitting diodes (figure 7, 160), a reflective surface (figure 7, 163), a light guide (figure 7, 162), a temperature monitor (figure 7, 192), temperature controller such as a fan (col.17, lines 41-43), means for flowing the fluid (figure 7, 170, 184, 186, and 188), container is a transparent plastic bag (col.28, example 12), container is a transparent rigid plastic container (figure 7, 164), a shaker table (col.9, line 57), photopermeable container contains photosensitizer prior to addition of fluid (col.18, lines 42-44) and a lowered plasma content than occurs naturally (col.13, lines 18-19).

With respect to claims 28-29, 51-52, 60-61 and 69, the ('337) reference adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. However, adjusting the plasma content to other concentration values is a matter of routine experimentation.

With respect to claims 3 and 39, the ('337) reference adjust the plasma content either before adding the photosensitizer or while adding the photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, the ('337) reference teaches diluting the plasma content (col.13, lines 18-19) such that it would be obvious to one having ordinary skill in the art to adjust the plasma either before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claim 14, the ('337) reference teaches washing or reducing the content of the plasma (col.13, lines 18-19). However, it would be obvious to one having ordinary skill in the art to wash the plasma as many times as required in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 24-25, the ('337) reference teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2) such that it would be obvious to use various ratios of visible and ultraviolet spectra in order for the radiation to completely inactivate microorganisms present therein.

With respect to claim 30, the ('337) reference teaches adjusting the content of plasma in the fluid, but fails to disclose such a range. However, adjusting the plasma content to other concentration values is a matter of routine experimentation.

With respect to claims 62-67, 70-74, and 105, such claims are already discussed above with regard to claims 16, 55-58, and 102.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

6. Claims 1-77, 104-105 and 107-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-6, 29 and 32 of copending Application No. 09/962,029 in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

This is a provisional obviousness-type double patenting rejection.

With respect to claims 1, 50, 59, 68, 104 and 107, claims 1, 3-6, 29 and 32 of copending Application No. 09/962,029 teaches a method for inactivating pathogens in a blood product including the addition of a photosensitizer to a blood thereby forming a mixture then exposing the mixture to pulses of light. However, the claims 1, 3-6, 29 and 32 of copending Application No. 09/962,029 fail to teach placing the fluid in a photopermeable container and adjusting the percentage of plasma in the fluid to a desired value such as the fluid contains a plasma content of between about 0% to about 50%. The ('337) reference teaches placing the fluid in a photopermeable container (col.25, lines 13-15) such that the cuvette is photopermeable (col.17, lines 39-40). In addition, the ('337) reference teaches adjusting the plasma (bilirubin) content to about 30% of the total volume (col.24, lines 51-61). The 30% volume is based on 70:30 volume-to-volume ratios for a total volume of 100 ml. Furthermore, the ('337) reference teaches (col.24, lines 49-62) adding the stock solution to a solution containing plasma only (100% content of plasma in the fluid). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the method claims of copending Application No. 09/962,029 to include a plasma adjustment step in order

to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 2, 4-13, 15-23, 26-27, 31-38, 40-49, 53-58, 75-77 and 108, the ('337) teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62), saline (col.13, line 13), buffer (col.13, line 13), nutrients (col.13, lines 16-19), phosphate (col.13, lines 27-28), cell storage solution (col.13, lines 16-19), an anticoagulant (col.12, lines 45-46), a cryoperservative solution (col.13, lines 25-29), washing the fluid (col.24, lines 60-62), photosensitizer is a photo-activatable compound (col.6, lines 4-10), photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.5, line 55), bacterial (col.4, line 15), HIV viruses (col.4, line 17), photoradiation in the visible spectrum (col.8, lines 64-65), photoradiation in the ultraviolet spectrum (col.8, line 63), photoradiation is in both the visible and ultraviolet spectra (col.8, lines 64-66), half the light in the visible spectrum and the other half in the ultraviolet spectrum (col.8, lines 66-67), plasma is adjusted to be within about 0 to about 50 percent of the total volume of the fluid (col.24, lines 60-62), photosensitizer is added to anticoagulant and the anticoagulant is added to the fluid (col.9, lines 65-67), enhancer is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5), adenine (col.10, line 5), flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56), fluid and photosensitizer are contained in a photoradiation transparent container (col.10, lines 55-56), agitating during exposing (col.9, lines 57-61), placing fluid in a container transparent to

photoradiation then adding photosensitizer to fluid and agitating the container (col.24, lines 60-62 and col.9, lines 57-61), adjusting the percentage of plasma before placing fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15), plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35), adding nutrients (coll13, lines 16-19), nutrients and photosensitizer are present in the container prior to addition of fluid (col.18, lines 42-44), blood constituents (col.4, line 41), whole blood (col.4, line 39), separated blood product (col.4, lines 41-43), consists essentially of platelets (col.24, lines 51-52), consists essentially of serum (col.4, lines 42-43), consists essentially of plasma (col.4, line 32), consists essentially of red blood cells (col.4, lines 41-42), adding sufficient additives so that proteins remains biologically active after exposing (col.10, lines 2-4), photosensitizer is present at a concentration of between about 1 to about 200 micromolar (col.24, lines 61-63), photoradiation is between about 400 and about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61), photoradiation is between about 100 and about 200 nm (col.9, lines 49-50), therapeutic protein (col.4, lines 44-45), factor VIII (col.4, line 46), a support surface substantially parallel to the source of light (figure 7, 164), light emitting diodes (figure 7, 160), a reflective surface (figure 7, 163), a light guide (figure 7, 162), a temperature monitor (figure 7, 192), temperature controller such as a fan (col.17, lines 41-43), means for flowing the fluid (figure 7, 170, 184, 186, and 188), container is a transparent plastic bag (col.28, example 12), container is a transparent rigid plastic container (figure 7, 164), a shaker table (col.9, line 57),

photopermeable container contains photosensitizer prior to addition of fluid (col.18, lines 42-44) and a lowered plasma content than occurs naturally (col.13, lines 18-19).

With respect to claims 28-29, 51-52, 60-61 and 69, the ('337) reference adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. However, adjusting the plasma content to other concentration values is a matter of routine experimentation.

With respect to claims 3 and 39, the ('337) reference adjusts the plasma content either before adding the photosensitizer or while adding the photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, the ('337) reference teaches diluting the plasma content (col.13, lines 18-19) such that it would be obvious to one having ordinary skill in the art to adjust the plasma either before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claim 14, the ('337) reference teaches washing or reducing the content of the plasma (col.13, lines 18-19). However, it would be obvious to one having ordinary skill in the art to wash the plasma as many times as required in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 24-25, the ('337) reference teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2) such that it would be obvious to use various ratios of visible and ultraviolet spectra in order for the radiation to completely inactivate microorganisms present therein.

With respect to claim 30, the ('337) reference teaches adjusting the content of plasma in the fluid, but fails to disclose such a range. However, it would be obvious to one having ordinary skill in the art to adjust the content of plasma in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present.

With respect to claims 62-67, 70-74 and 105, such claims are already discussed above with regard to claims 16, 55-58, and 102.

7. Claims 1-77, 104-105 and 107-108 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 31-38 of copending Application No. 10/357,599 in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

This is a provisional obviousness-type double patenting rejection.

With respect to claims 1, 50, 59, 68, 104 and 107, claims 1-11 and 31-38 of copending Application No. 10/357,599 teach a method for inactivating pathogens in a fluid containing blood product including the addition of a photosensitizer to a blood thereby forming a mixture then irradiating the mixture with pulses of light. However, the claims 1-11 and 31-38 of copending Application No. 10/357,599 fail to teach placing the fluid in a photopermeable container and adjusting the percentage of plasma in the fluid to a desired value such as the fluid contains a plasma content of between about 0% to about 50%. The ('337) reference teaches placing the fluid in a photopermeable container (col.25, lines 13-15) such that the cuvette is photopermeable (col.17, lines 39-40). In addition, the ('337) reference teaches adjusting the plasma (bilirubin) content to

about 30% of the total volume (col.24, lines 51-61). The 30% volume is based on 70:30 volume-to-volume ratios for a total volume of 100 ml. Furthermore, the ('337) reference teaches (col.24, lines 49-62) adding the stock solution to a solution containing plasma only (100% content of plasma in the fluid). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the method claims of copending Application No. 10/357,599 to include a plasma adjustment step in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 2, 4-13, 15-23, 26-27, 31-38, 40-49, 53-58, 75-77 and 108, the ('337) teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62), saline (col.13, line 13), buffer (col.13, line 13), nutrients (col.13, lines 16-19), phosphate (col.13, lines 27-28), cell storage solution (col.13, lines 16-19), an anticoagulant (col.12, lines 45-46), a cryoperservative solution (col.13, lines 25-29), washing the fluid (col.24, lines 60-62), photosensitizer is a photo-activatable compound (col.6, lines 4-10), photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.5, line 55), bacterial (col.4, line 15), HIV viruses (col.4, line 17), photoradiation in the visible spectrum (col.8, lines 64-65), photoradiation in the ultraviolet spectrum (col.8, line 63), photoradiation is in both the visible and ultraviolet spectra (col.8, lines 64-66), half the light in the visible spectrum and the other half in the ultraviolet spectrum (col.8, lines 66-67), plasma is adjusted to be within about 0 to about 50 percent of the total volume of the fluid (col.24,

lines 60-62), photosensitizer is added to anticoagulant and the anticoagulant is added to the fluid (col.9, lines 65-67), enhancer is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5), adenine (col.10, line 5), flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56), fluid and photosensitizer are contained in a photoradiation transparent container (col.10, lines 55-56), agitating during exposing (col.9, lines 57-61), placing fluid in a container transparent to photoradiation then adding photosensitizer to fluid and agitating the container (col.24, lines 60-62 and col.9, lines 57-61), adjusting the percentage of plasma before placing fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15), plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35), adding nutrients (coll13, lines 16-19), nutrients and photosensitizer are present in the container prior to addition of fluid (col.18, lines 42-44), blood constituents (col.4, line 41), whole blood (col.4, line 39), separated blood product (col.4, lines 41-43), consists essentially of platelets (col.24, lines 51-52), consists essentially of serum (col.4, lines 42-43), consists essentially of plasma (col.4, line 32), consists essentially of red blood cells (col.4, lines 41-42), adding sufficient additives so that proteins remains biologically active after exposing (col.10, lines 2-4), photosensitizer is present at a concentration of between about 1 to about 200 micromolar (col.24, lines 61-63), photoradiation is between about 400 and about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61), photoradiation is between about 100 and about 200 nm (col.9, lines 49-50), therapeutic protein (col.4, lines 44-45), factor VIII (col.4, line 46), a support surface substantially parallel to the source of light (figure 7,

164), light emitting diodes (figure 7, 160), a reflective surface (figure 7, 163), a light guide (figure 7, 162), a temperature monitor (figure 7, 192), temperature controller such as a fan (col.17, lines 41-43), means for flowing the fluid (figure 7, 170, 184, 186, and 188), container is a transparent plastic bag (col.28, example 12), container is a transparent rigid plastic container (figure 7, 164), a shaker table (col.9, line 57), photopermeable container contains photosensitizer prior to addition of fluid (col.18, lines 42-44) and a lowered plasma content than occurs naturally (col.13, lines 18-19).

With respect to claims 28-29, 51-52, 60-61 and 69, the ('337) reference adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. However, adjusting the plasma content to other concentration values is a matter of routine experimentation.

With respect to claims 3 and 39, the ('337) reference adjusts the plasma content either before adding the photosensitizer or while adding the photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, the ('337) reference teaches diluting the plasma content (col.13, lines 18-19) such that it would be obvious to one having ordinary skill in the art to adjust the plasma either before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claim 14, the ('337) reference teaches washing or reducing the content of the plasma (col.13, lines 18-19). However, it would be obvious to one having ordinary skill in the art to wash the plasma as many times as required in order to

prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 24-25, the ('337) reference teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2) such that it would be obvious to use various ratios of visible and ultraviolet spectra in order for the radiation to completely inactivate microorganisms present therein.

With respect to claim 30, the ('337) reference teaches adjusting the content of plasma in the fluid, but fails to disclose such a range. However, it would be obvious to one having ordinary skill in the art to adjust the content of plasma in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present.

With respect to claims 62-67, 70-74 and 105, such claims are already discussed above with regard to claims 16, 55-58, and 102.

8. Claims 78-103 and 106 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-30 of copending Application No. 10/357,599 in view of Goodrich, Jr. et al (U.S.P.N. 6,277,337).

This is a provisional obviousness-type double patenting rejection.

With respect to claims 78, 84, 97-98 and 106, claims 12-30 of copending Application No. 10/357,599 teach a treatment chamber for inactivating pathogens in a blood product fluid and a photosensitizer including the following: at least one radiation source for irradiating the fluid, a support platform for holding the fluid to be irradiated

(means for maintaining), a photopermeable container that includes both the fluid and the photosensitizer and a support platform moves in multiple directions (means for mixing or agitating). However, claims 12-30 of copending Application No. 10/357,599 fail to teach the following: a fluid in a container having a portion of the plasma removed, means for adjusting the plasma, a photopermeable container in fluid communication with the means for adding the photosensitizer and means for adjusting the plasma content and means for producing selected flow rate. With respect to claims 78, 84, 97-98 and 106, the ('337) reference teaches an apparatus for inactivating microorganisms in fluids (col.3, lines 59-65) including the following: adjusting (i.e., removing) the percentage of plasma or bilirubin (col.24, line 51), mixing (col.24, lines 56-58), exposing the fluid to photoradiation (col.24, lines 64-65), a source of light (figure 7, 160), means for maintaining the fluid in the light path (figure 7, 164 and col.17, lines 39-41), a container (figure 7, 164, col.13, lines 6-8, and col.24, line 51), means for adjusting the plasma content of the fluid (col.24, lines 49-52), means for mixing (figure 7, 186), a photopermeable container (figure 7, 164 and col.13, lines 18-19) in fluid communication with the means for adding the photosensitizer and means for adjusting the plasma content, means for producing selected flow rate (figure 7, 184) and means for agitating the container (col.8, lines 34-36). Thus, it would have obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus claims of copending Application No. 10/357,599 to include means for adjusting the plasma content in order to examine the impact of the plasma adjustment step on the platelet quality post-treatment ('337, col.23, lines 19-21).

With respect to claims 79-83, 85-96 and 99-103, the ('337) reference teaches the following: photosensitizer is a photo-activatable compound (col.6, lines 4-10), photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.5, line 55), photoradiation in the visible spectrum (col.8, lines 64-65), photoradiation in the ultraviolet spectrum (col.8, line 63), photoradiation is in both the visible and ultraviolet spectra (col.8, lines 64-66), half the light in the visible spectrum and the other half in the ultraviolet spectrum (col.8, lines 66-67), plasma is adjusted to be within about 0 to about 50 percent of the total volume of the fluid (col.24, lines 60-62), photosensitizer is added to anticoagulant and the anticoagulant is added to the fluid (col.9, lines 65-67), enhancer is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5), flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56), fluid and photosensitizer are contained in a photoradiation transparent container (col.10, lines 55-56), agitating during exposing (col.9, lines 57-61), placing fluid in a container transparent to photoradiation then adding photosensitizer to fluid and agitating the container (col.24, lines 60-62 and col.9, lines 57-61), adjusting the percentage of plasma before placing fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15), plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35), nutrients and photosensitizer are present in the container prior to addition of fluid (col.18, lines 42-44), blood constituents (col.4, line 41), whole blood (col.4, line 39), separated blood product (col.4, lines 41-43), consists essentially of platelets (col.24, lines 51-52), consists essentially of serum (col.4, lines 42-43), consists essentially of plasma (col.4, line 32), consists essentially of red blood cells (col.4, lines 41-42), adding

sufficient additives so that proteins remains biologically active after exposing (col.10, lines 2-4), a support surface substantially parallel to the source of light (figure 7, 164), light emitting diodes (figure 7, 160), a reflective surface (figure 7, 163), a light guide (figure 7, 162), a temperature monitor (figure 7, 192), temperature controller such as a fan (col.17, lines 41-43), means for flowing the fluid (figure 7, 170, 184, 186, and 188), container is a transparent plastic bag (col.28, example 12), container is a transparent rigid plastic container (figure 7, 164), a shaker table (col.9, line 57), photopermeable container contains photosensitizer prior to addition of fluid (col.18, lines 42-44) and a lowered plasma content than occurs naturally (col.13, lines 18-19).

Claim Rejections - 35 USC § 102

9. Claims 1-2, 4-13, 15-23, 26-27, 31-38, 40-50, 53-59, 68, 75-104 and 106-108 are rejected under 35 U.S.C. 102(e) as being anticipated Goodrich, Jr. et al (U.S.P.N. 6,277,337).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference (July 21, 1998), it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With respect to claims 1, 50, 59, 68, 78, 84, 97-98, 104 and 106-107, the ('337) reference discloses a method and an apparatus for inactivating microorganisms in fluids

(col.3, lines 59-65) including the following: adjusting (i.e., removing) the percentage of plasma or bilirubin (col.24, line 51), mixing (col.24, lines 56-58) and exposing the fluid to photoradiation (col.24, lines 64-65). In addition, the ('337) reference teaches adjusting the plasma (bilirubin) content to about 30% of the total volume (col.24, lines 51-61). The 30% volume is based on 70:30 volume-to-volume ratios for a total volume of 100 ml. Furthermore, the ('337) reference teaches (col.24, lines 49-62) adding the stock solution to a solution containing plasma only (100% content of plasma in the fluid). Further the ('337) reference discloses the following: a source of light (figure 7, 160), means for maintaining the fluid in the light path (figure 7, 164 and col.17, lines 39-41), a container (figure 7, 164, col.13, lines 6-8, and col.24, line 51), means for adjusting the plasma content of the fluid (col.24, lines 49-52), means for mixing (figure 7, 186), a photopermeable container (figure 7, 164 and col.13, lines 18-19), means for producing selected flow rate (figure 7, 184) and means for agitating the container (col.8, lines 34-36).

With respect to claims 2, 4-13, 15-23, 26-27, 31-38, 40-49, 53-58, 75-77, 79-83, 85-96, 99-103 and 108, the ('337) reference teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62), saline (col.13, line 13), buffer (col.13, line 13), nutrients (col.13, lines 16-19), phosphate (col.13, lines 27-28), cell storage solution (col.13, lines 16-19), an anticoagulant (col.12, lines 45-46), a cryoperservative solution (col.13, lines 25-29), washing the fluid (col.24, lines 60-62), photosensitizer is a photo-activatable

compound (col.6, lines 4-10), photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.5, line 55), bacterial (col.4, line 15), HIV viruses (col.4, line 17), photoradiation in the visible spectrum (col.8, lines 64-65), photoradiation in the ultraviolet spectrum (col.8, line 63), photoradiation is in both the visible and ultraviolet spectra (col.8, lines 64-66), half the light in the visible spectrum and the other half in the ultraviolet spectrum (col.8, lines 66-67), plasma is adjusted to be within about 0 to about 50 percent of the total volume of the fluid (col.24, lines 60-62), photosensitizer is added to anticoagulant and the anticoagulant is added to the fluid (col.9, lines 65-67), enhancer is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5), adenine (col.10, line 5), flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56), fluid and photosensitizer are contained in a photoradiation transparent container (col.10, lines 55-56), agitating during exposing (col.9, lines 57-61), placing fluid in a container transparent to photoradiation then adding photosensitizer to fluid and agitating the container (col.24, lines 60-62 and col.9, lines 57-61), adjusting the percentage of plasma before placing fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15), plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35), adding nutrients (coll13, lines 16-19), nutrients and photosensitizer are present in the container prior to addition of fluid (col.18, lines 42-44), blood constituents (col.4, line 41), whole blood (col.4, line 39), separated blood product (col.4, lines 41-43), consists essentially of platelets (col.24, lines 51-52), consists essentially of serum (col.4, lines 42-43), consists essentially of plasma (col.4, line 32), consists essentially of red blood cells (col.4, lines 41-42), adding sufficient additives so that proteins remains

biologically active after exposing (col.10, lines 2-4), photosensitizer is present at a concentration of between about 1 to about 200 micromolar (col.24, lines 61-63), photoradiation is between about 400 and about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61), photoradiation is between about 100 and about 200 nm (col.9, lines 49-50), therapeutic protein (col.4, lines 44-45), factor VIII (col.4, line 46), a support surface substantially parallel to the source of light (figure 7, 164), light emitting diodes (figure 7, 160), a reflective surface (figure 7, 163), a light guide (figure 7, 162), a temperature monitor (figure 7, 192), temperature controller such as a fan (col.17, lines 41-43), means for flowing the fluid (figure 7, 170, 184, 186, and 188), container is a transparent plastic bag (col.28, example 12), container is a transparent rigid plastic container (figure 7, 164), a shaker table (col.9, line 57), photopermeable container contains photosensitizer prior to addition of fluid (col.18, lines 42-44), and a lowered plasma content than occurs naturally (col.13, lines 18-19).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 3, 14, 24-25, 28-30, 39, 51-52, 60-67, 69-74 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,277,337).

With respect to claims 28-29, 51-52, 59, 60-61, and 68-69, the ('337) adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. However, it would be obvious to one having ordinary skill in the art to modify the plasma content in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein even if such an adjustment is not taught in the reference.

With respect to claims 3 and 39, the ('337) reference adjusts the plasma content either before adding the photosensitizer or while adding the photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, the ('337) reference diluting the plasma content (col.13, lines 18-19) such that it would be

obvious to one having ordinary skill in the art to adjust the plasma either before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claim 14, the ('337) reference teaches washing or reducing the content of the plasma (col.13, lines 18-19). However, it would be obvious to one having ordinary skill in the art to wash the plasma as many times as required in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 24-25, the ('337) reference teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2) such that it would be obvious to use various ratios of visible and ultraviolet spectra in order for the radiation to completely inactivate microorganisms present therein.

With respect to claim 30, the ('337) reference teaches adjusting the content of plasma in the fluid, but fails to disclose such a range. However, it would be obvious to one having ordinary skill in the art to adjust the content of plasma in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 62-67, 70-74, and 105, such claims are already discussed above with regard to claims 16, 55-58, and 102.

Response to Arguments

14. Applicant's arguments with respect to claims 1-108 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Platz et al (U.S.P.N. 6,268,120), McBurney et al (U.S.P.N. 6,548,241), Platz et al (U.S.P.N. 6,187,572) and Sowemimo-Coker et al (U.S.P.N. 6,235,508) teach similar concepts in inactivating fluids, which contains microorganisms.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
08/19/2004

Robert J. Warden Sr.
ROBERT J. WARDEN, SR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700